

## **CDC 75I- isopropyl alcohol liquid**

### **Friendo LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **Hand Sanitizer**

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Isopropyl Alcohol (75.4%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. PVP K90 (1.4% v/v).
- c. Sterile distilled water or boiled cold water (23.2% v/v).

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

### **Active Ingredient(s)**

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Sanitizer

### **Use**

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

### **Warnings**

For external use only. Flammable. Keep away from heat or flame

### **Do not use**

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

## Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

## Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

## Inactive ingredients

PVP K90, purified water USP

## Package Label - Principal Display Panel



### ***Drug Facts***

#### ***Active Ingredient***

Isopropyl Alcohol (75% v/v)

#### ***Purpose***

Antiseptic

#### ***Uses***

■ For handwashing to decrease bacteria on the skin. ■ Recommended for repeated use.

#### ***Warnings***

**For external use only-hands**

**Flammable. Keep away from heat and flame.**

**When using this product** ■ Keep out of eyes. In case of contact with eyes, flush thoroughly with water. ■ Avoid contact with broken skin. ■ Do not inhale or digest.

**Stop use and ask a doctor if skin irritation develops.**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

***Directions*** ■ Wet hands thoroughly with product and allow to dry without wiping. ■ For children under 6, use only under adult supervision. ■ Not recommended for infants.

***Other Information*** ■ Do not store above 105°F. ■ May discolor some fabrics. ■ Harmful to wood finishes and plastics.

***Inactive Ingredients*** ■ 1-Ethenyl-2-pyrrolidon polymer, Water

#### **Distributed By:**

Friendo LLC  
4285 TW King Road  
Southlake TX 76092



**CDC 75I**

isopropyl alcohol liquid

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	
Route of Administration		TOPICAL		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)			ISOPROPYL ALCOHOL	0.754 L in 1 L
Inactive Ingredients				
Ingredient Name			Strength	
POVIDONE K90 (UNII: RDH86HJV5Z)			0.014 L in 1 L	
WATER (UNII: 059QF0KO0R)			0.232 L in 1 L	
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74238-100-20	0.059 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
2	NDC:74238-100-21	0.237 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
3	NDC:74238-100-22	1.89 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
4	NDC:74238-100-23	4 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
5	NDC:74238-100-24	208.2 L in 1 DRUM; Type 0: Not a Combination Product	03/31/2020	
6	NDC:74238-100-25	1041 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/31/2020	
7	NDC:74238-100-26	1249 L in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	03/31/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	03/31/2020	

**Labeler** - Friendo LLC (926569711)

**Registrant** - Friendo LLC (926569711)

## Establishment

Name	Address	ID/FEI	Business Operations
Friendo LLC		926569711	manufacture(74238-100)

